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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,451	04/03/2001	Toshikazu Hirayama	010477	3311
23850	7590	04/20/2004	EXAMINER	
ARMSTRONG, KRATZ, QUINTOS, HANSON & BROOKS, LLP 1725 K STREET, NW SUITE 1000 WASHINGTON, DC 20006			LAM, ANN Y	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/821,451	TOSHIKAZU HIRAYAMA	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Discko, Jr., 5,267,859, in view of Stanners et al., 5,330, 440.

Discko, Jr. discloses a barrel (16) which is provided with a nozzle mounting portion at a distal end thereof; a plunger (20) which is inserted from a proximal end of said barrel; and a nozzle (12) which is freely detachable with said nozzle mounting portion, wherein said nozzle includes a mounting portion on the proximal end side which is provided with means (126) for mounting to said nozzle mounting portion, and a discharging portion (130 and 140) which extends bending at a predetermined angle from this mounting portion, wherein said discharging portion located at a distal end side of a bended portion of said nozzle is formed so as to become thinner at a tip thereof in a tapered shape, See Figure 3 (or alternatively, Figure 4, 5 or 6.)

However, Discko does not disclose that the plunger is provided with a gasket capable of sliding hermetically along an inner wall of the barrel at a distal end thereof.

Stanners discloses that gaskets (6a and 6b) are used to encircle a piston to create a seal (column 7, lines 56-57.) It would have been obvious to provide a gasket in the Discko device in order to create a seal as taught by Stanners around the plunger as would be desirable for expelling material. (The Discko plunger is equivalent to the Stanners piston, since they serve the same purpose of expelling material.)

Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Discko, Jr., 5,267,859, in view of Stanners et al., 5,330, 440, as applied to claim 1 above, and further in view of Utterberg, 5,047,021.

Discko in view of Stanners discloses the invention substantially as claimed (see above), including a means to connect the nozzle to the barrel (see Discko, Figure 10 for example). However, Discko does not disclose that the connection means is a luer lock connection.

Utterberg discloses that luer locks are well known in the art to connect disposable medical devices (column 1, lines 15-16.)

As to claim 4, the female threads are integrally formed with the barrel (column 1, line 45.)

As to claim 5, the female threads are disposed in a freely rotatable condition on the outer wall of the barrel (column 1, line 47.)

It would have been obvious to provide the luer locks as disclosed by Utterberg to connect the nozzle to the barrel in the Discko-Stanners device as an alternative means to connect disposable medical devices as taught by Utterberg.

Response to Arguments

In response to Applicant's brief, Examiner has changed the rejections as described above.

With respect to claim 1, Applicant's arguments are not considered persuasive. Applicant argues on page 5 that the rejection is nearly identical to the rejection of October 23, 2002, which was subsequently overcome, and Applicant questions whether it is permissible for Examiner to recycle a rejection in the manner of this case.

In response, Examiner would like to point out that subsequent to the rejection of October 23, 2002, Applicant amended the claims, adding the limitations recited in the last two lines of the claim. Thus, the Discko rejection in the previous rejection (as well as in the current rejection) is different from the Discko rejection of October 23, 2002.

Applicant also argues on page 6 that Discko nowhere discloses that the nozzle (32) is removable from the body portion (30). In response, Examiner points out that nozzle (32) is not the nozzle used in the rejection. The nozzle used in the rejection is disclosed at (12), (see rejection of claim 1 above.)

Applicant also argues on page 7 that there is no description of any gasket inside the cartridge and apparently the piston (28) does not need one because the material M is viscous. The arguments have been considered but are moot in view of the new ground(s) of rejection.

With respect to Applicant's arguments regarding claims 3-5, the arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



LONG V. LE
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04/19/07